Products Medical Devices



Brian Ludovico E-Mail: bludovico@us.tuv.com

May 31, 2018

Mr. Kim Myung-Sub
DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
CHUNGCHEONGBUK-DO, 28161
REPUBLIC OF KOREA

RE: ISO 13485:2003 Re-certification Audit 74 500 5179

Dear Mr. Myung-Sub,

Thank you for your patience and kind support during the ISO 13485:2003 registration process. Please find the certificate stating compliance to the ISO 13485:2003 enclosed.

In addition, a copy of our ISO 13485:2003 certification mark can be obtained by contacting us directly.

Please don't hesitate to contact us if you have any further questions or concerns.

Sincerely

M.Sc. M. Aihara Certification Officer

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Medical Division

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Member of TÜV Rheinland Group

Certificate



TUV Rheinland of North America, Inc., a CMDCAS recognized registrar, certifies that

> **DiaDent Group International** 16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongiu-si Chungcheongbuk-do, 28161 Republic of Korea

has established and maintained a

Quality Management System according to ISO 13485:2003

Audit Report No.: 12022722 005 Certificate Registration No.: 74 500 5179

Expiry Date:

December 31, 2018

see attachment for products covered by this registration



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Certification Officer: M.Sc. M. Aihara

TUV Rheinland of North America, Inc. Newtown, Connecticut

Effective Date: June 01, 2018



Attachment

Quality Management System according to ISO 13485:2003

for

DiaDent Group International 16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si Chungcheongbuk-do, 28161 Republic of Korea

The products covered by this registration:

Design and Development, Manufacture, Distribution and Service of Gutta Percha Obturation Systems, Curing Lights

Design and Development, Manufacture and Distribution of Gutta Percha Points, Absorbent Paper Points, Calciumhydroxide Material and Special Syringes for Dental Applications, Dental Composite Restorative Materials, Pit and Fissure Sealant, Bonding Agents, Light-cured Temporary Filling Material, EDTA Root Canal Preparation Cream (PerioDontic, Endodontic Irrigating Syringe), Root Canal Filling Material, Phosphoric Etching Gel, Endodontic Files, Disposable Sterile Irrigation Probe Needle Tips, Dental Temporary Cement, Dual-cured Composite, Hydraulic Temporary Restorative Material and Root Canal Sealing Material

Audit Report No.:

Certificate Registration No.:

Expiry Date:

12022722 005

74 500 5179

December 31, 2018



Certification Officer: M.Sc. M. Aihara

TUV Rheinland of North America, Inc.

Newtown, Connecticut

Effective Date: June 01, 2018

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